

Statement of Rep. Tom Davis
Ranking Republican Member
Committee on Oversight and Government Reform
“FDA’s Critical Mission and Challenges for the Future”
May 1, 2007

Thank you Mr. Chairman for holding today’s hearing to consider the critical mission of the Food and Drug Administration (FDA) and the many challenges the agency faces keeping pace with rapidly evolving science and an increasingly global marketplace. This is a very important subject worthy of this Committee’s continued attention.

The FDA’s basic mission is to promote and protect public health by approving and monitoring the marketing of safe and effective products. The agency is also responsible for providing current, science-based information to the public on key health issues. But in recent years, the FDA has stumbled through some high-profile missteps. The withdrawal of the painkiller Vioxx caused many to ask if drugs were being approved too fast and monitored too little after reaching the marketplace. The shortage of vaccine for the 2004-2005 flu season raised questions about how best to regulate and stimulate production of biopharmaceutical products. And, the FDA role in food safety arose again when E-coli contamination was found in fresh spinach last year, and most recently with the nation-wide recall of Peter Pan peanut butter.

Most Americans believe that once something gets FDA approval, it carries the federal government equivalent of the Good Housekeeping Seal of Approval, and can be used without worry or risk. We need to be sure that confidence is not misplaced, or grounded only on the legend of an infallible FDA or the myth of risk free products. We should indulge neither legend nor myth when entrusting critical questions of safety, efficacy and risk to federal decision makers. But we should do everything possible to ensure the FDA has the statutory tools, the talent and the resources necessary to operate effectively, efficiently and transparently. No one should have any cause to doubt that, even if they sometimes get it wrong, the FDA is guided only by the best science available and acts solely in the interest of the American consumer.

At stake in the FDA getting it right: the health and safety of the American people and the viability of a huge and growing sector of our economy. Industries regulated by the FDA generate hundreds of billions of dollars in sales revenue, support important research and create high-value jobs. Continued loss of confidence in the FDA takes us down a path we simply cannot afford, either financially or in terms of public health. The FDA has to stand as the trusted, unbiased, vigilant watchdog over the nation's food and drug supply.

Nevertheless, recent high-profile recalls and contaminations heightened concerns about the capability and credibility of the federal agency charged to assure the safety and effectiveness of so many medicines, foods, cosmetics and other products millions of Americans use every day. So we ask: How can we strengthen the security and safety of foods that now travel around our country and across the world with unprecedented speed? How can FDA work with regulated industries to better ensure the safety of approved drugs and medical devices? What can be done to improve product manufacturing and handling practices? How can post-marketing surveillance of approved products be strengthened, and who will pay for it? And do current adverse event reporting systems capture the reliable and timely data FDA needs to inform sound regulatory decisions?

This Committee has looked at some of these questions before. As Chairman, I convened similar oversight hearings on drug safety and post-marketing surveillance issues surrounding the withdrawal of Vioxx from the market. We also investigated FDA oversight of reprocessed single-use medical devices. Hearings were held on efforts to address the growing problem of illegal pharmacy websites. And, we have closely monitored food safety and dietary supplement issues. Our investigation into the flu vaccine shortage resulted in more frequent on-site FDA inspections of vaccine manufacturing facilities. With regard to this range of issues, it can't be said Republicans did no oversight for six years.

So I am happy Chairman Waxman chose to keep our focus on these important questions. He believes fervently in the need for a strong, independent and effective FDA, and has worked over many years to sustain and strengthen the agency's capabilities. Given that bipartisan consensus, I look forward to a thoughtful discussion today on the future of the FDA and how to address the many and complex challenges faced by that critical federal agency.

We are very fortunate to have before us such a distinguished panel of witnesses. All have held the top leadership post at the FDA and share invaluable experience running one of the nation's most important public health and consumer protection agencies. I look forward to their testimony, their insights and their perspectives.